

AUG 23 2000

K 000355

Annex 5.

510(k) Summary

3M™ Comply™ 1249 Liquid Peracetic Acid Chemical Indicator

Manufacturer: 3M Medical Products
3M Center
St. Paul, Minnesota 55144-1000

Regulatory Affairs Contact: Gretchen Keenan, RAC
Product Regulation Manager
3M Medical-Surgical Division
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144-1000

Telephone: (651) 733-7605

Date Summary Prepared: February 1, 2000

Device Trade Name: 3M™ Comply™ 1249 Liquid Peracetic Acid Chemical Indicator

Common or Usual Name: Chemical indicator

Classification: Class II Medical Device

Intended Use: The Comply 1249 Liquid Peracetic Acid Chemical Indicator is specifically designed for use in a STERIS SYSTEM 1™ Processor with STERIS 20™ Sterilant to detect peracetic acid concentration at initial point of contact.

Description: The 3M Comply 1249 Liquid Peracetic Acid Chemical Indicator is a qualitative, single-use, indicator that is designed to detect peracetic acid concentration in the STERIS SYSTEM 1 Processor at initial point of contact. The indicator consists of a plastic bubble that is heat sealed to vapor permeable material. A red chemical circle that reacts to peracetic acid is encased within this heat sealed system.

Substantial Equivalence: 3M Comply 1249 Liquid Peracetic Acid Chemical Indicator is substantially equivalent to STERIS PROCESS™ Chemical Monitoring Strip (K921559, February 28, 1995).

Testing Summary: Test results from the following studies have been included in the 510(k) submission for the subject product to support a determination of substantial equivalence:

TEST

Visual and Spectrophotometric Assessment

RESULT

Overall, Comply 1249 was accurately interpreted 92% of the time, while the Steris Chemical Monitoring Strip was correctly read only 51% of the time.

This study also confirmed that Comply 1249 is capable of maintaining its final reading after exposure to peracetic acid in the Steris System 1 Processor for at least 30 minutes, significantly longer than the Steris Chemical Monitoring Strip

Leaching Study

No significant amounts of Comply 1249 indicator chemistry leached out of the indicator's plastic containment system under conditions similar to the Steris System 1 Processor.

Two Year Aging Study in Unopened Packaging

Two year aging of Comply 1249 in unopened packaging was initiated on 12/17/99. Shelf life claims may be amended based on results of this study.

Ten Week Aging Study in Opened/Resealed Packaging

Ten week aging in opened and resealed packaging of Comply 1249 was initiated 12/23/99. Shelf Life claims may be amended based on the results of this study.

Color Change Progression of Comply 1249 Over Varying Sterilant Concentrations

Study results support the spectrophotometric data for progression of color response of Comply 1249 in varying concentrations of Steris 20 Sterilant Concentrate in the Steris System 1 Processor.

Interfering Substances

This study demonstrates that hard water and organic burden do not interfere with the efficacy Comply 1249.

Visual Interpretation of Monitors at Three Time Intervals

Results demonstrate that Comply 1249 has a high sensitivity at time zero. However, color interpretation becomes less reliable at time points greater than 30 minutes after cycle completion.

STERIS SYSTEM 1, STERIS 20, and STERIS PROCESS are trademarks of the STERIS Corporation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 23 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Gretchen Keenan
Product Regulation Manager
3M Health Care
3M Medical-Surgical Division
Building 275-5 3M Center
Saint Paul, Minnesota 55077

Re: K000355
Trade Name: 3M Comply 1249 Liquid Peracetic Acid
Chemical Indicator
Regulatory Class: II
Product Code: JOJ
Dated: May 12, 2000
Received: May 31, 2000

Dear Ms. Keenan:

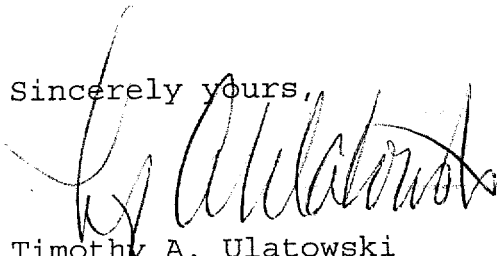
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Annex 4.

Indications for Use Enclosure

510(k) Number (if known): K000355

Device name:

3M™ Comply™ 1249 Liquid Peracetic Acid Chemical Indicator

Indications for Use:

The Comply 1249 Liquid Peracetic Acid Chemical Indicator is specifically designed for use in a STERIS SYSTEM 1 Processor with STERIS 20 Sterilant to detect peracetic acid concentration at initial point of contact.

(PLEASE DO NOT WRITE BELOW THIS LINE, CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

OR Over the Counter Use

(Per 21 CFR 801.109)

Chin S. Lim
(Division Sign-Off)

(Optional Format 1-2-96)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number

K000355